



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,282	06/18/2002	D. Laksen Sirimanne	DEV-5247USPCT	2605

21884 7590 01/05/2011  
WELSH FLAXMAN & GITLER LLC  
2000 DUKE STREET, SUITE 100  
ALEXANDRIA, VA 22314

EXAMINER
----------

WEATHERBY, ELLSWORTH

ART UNIT	PAPER NUMBER
----------	--------------

3768

MAIL DATE	DELIVERY MODE
-----------	---------------

01/05/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/869,282	SIRIMANNE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ELLSWORTH WEATHERBY	3768	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 237-260 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 237-260 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 90-94, 97-99, 101-137, 154-159 and 166-168 of copending Application No. 10/960,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker at the center of the body, where the marker can be a wire, radiopaque or echogenic. Although the present invention and the ‘622 application differ in that the present invention teaches that the second material comprises unitary piece of metal and the ‘622 application

Art Unit: 3768

teaches a wire. The examiner stands that one of ordinary skill in the art would recognize that similarity and interchangeability between a wire and a unitary piece of metal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claim 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 22-24, 31, 33, 111-123 of copending Application No. 09/805,652. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a device for implanting a marker device comprising a metallic marker and a bioabsorbable or porous filler body. Because of the extent of overlapping subject matter, the Examiner stands that it would be obvious to one of ordinary skill in the art to recognize that biocompatible suture-type material with a metallic marker disposed therein would be an equivalent to the subcutaneous marking device of claim 1, for example, comprising at least two implantable bodies it would have been obvious to have provided at least two bodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 77-97 and 100-104, 107-110 of copending Application No. 10/114,712. Although the conflicting claims

Art Unit: 3768

are not identical, they are not patentably distinct from each other because both claim substantially the same subject matter comprising a marker that comprises a bioabsorbable filler with a detectable, where the marker can be a wire, metallic, and/or radiopaque. Although the 10/114,712 application does not expressly disclose an apparatus deploying the marker, it would have been obvious to one of ordinary skill in the art who is in possession of a marker to deploy the marker using any known elongate puncture or catheter device.

5. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/961,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim substantially the same subject matter comprising a marker that comprises a bioabsorbable filler with a detectable, where the marker can be a wire, metallic, and/or radiopaque.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/961,581. Although the conflicting claims are not identical,

Art Unit: 3768

they are not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material.

The present invention claims that the marker device comprises two materials and the '581 application claims introducing into the first material the second material (e.g. claims 14-15). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/241,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material including bioabsorbable material and a metallic material. The present invention claims that the marker device comprises two materials, a suture type bioabsorbable material and the '581 application claims a collagenous first material and a metallic second material (e.g. claims 3-4). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 3768

9. Claims 237-260 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/283,310. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material including bioabsorbable material and a metallic material. The present invention claims an insertion device and that the marker device comprises two materials, a suture type bioabsorbable material and the '310 application claims the insertion device and a bioabsorbable matrix and a radiographically detectable second material (e.g. claims 1-4). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

10. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 244 and 250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/960,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a marking device to be inserted the body where the marker comprises at least one material. The present invention claims that the marker device comprises a bioabsorbable suture and a metal and the '618 application claims a detectable marker suspended in a bioabsorbable filler

Art Unit: 3768

body. The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 237-260 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11-15, 17, 26-39, 43-61, 65-80, 87, 90-102 of U.S. Patent No. 6,371,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker that comprises metal.

13. Claim 237-260 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 18-26, 29-42, 84-111 of U.S. Patent No. 6,356,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker that comprises metal.

14. Claims 244-260 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,668,582.



Art Unit: 3768

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a two component biocompatible marker. Although the present application claims a bioabsorbable suture material and the '582 patent claims a gelatin, the examiner stands that any differences are obvious variations easily recognizable by one of ordinary skill in the art.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 237-240, 241-258, 260 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton et al. (Pub. No.: 2002/0058883) in view of Herweck et al. (USPN 5,320,100).

17. Fulton teaches a Biopsy Localization method and device (Abstract; Figs. 1-7). Here, Fulton teaches an elongate member having a distal portion and a proximal portion with a lumen extending between the distal and proximal portion, the distal portion of the elongate member configured to seat the marking device and advance the marking device with the distal portion to the target site (0022; See: Figs. 3-7: e.g. a TrueCut type biopsy needle, a needle, or rotational vacuum assisted biopsy probe); an ejector coupled to the elongate member, said ejector configured to disengage the marking

Art Unit: 3768

device from the distal portion (See: Figs. 3-7 as noted above); a marking device preloaded and in contact with the elongate member distal portion interior walls, for delivery through the distal portion (Abstract; 0007); wherein the marking device comprises a first component (e.g. collagen), where the first component is a flexible bioabsorbable suture material (0007-0008; 0029; 0033: Here, the Examiner stands that collagen sutures are well known to one of ordinary skill in the art at the time of the invention); and the second component is a marker, wherein the second component is carried by the first component (0028; claims 7-8 ). Fulton also teaches treating the first component so that it is echogenic (0011).

18. Fulton does not expressly teach that the marker is formed from a unitary piece of metal. However, the examiner stands that Fulton's disclosure, "For the device to be detected by mammography, it would have to be radiopaque and probably contain iodine or other radiopaque material (re-sorbable or not re-sorbable)." That is, in the field of implantable devices, the obviousness of the similarities and interchangeability of wires, metals, radioactive boluses, powders, and the like that are well known to enhance the visibility or applicability of otherwise non-radiopaque or MR imagable implants or devices would be apparent to one of ordinary skill in the art. However, Fulton does not expressly teach that the second material is metal.

19. In a related field of endeavor, Herweck et al. (hereinafter Herweck) teaches an implantable device having integral patency diagnostic indicia (Abstract; Figs. 1-3). Herweck goes on, expressly disclosing that various remotely detectable materials are generally known that are suitable for disposition in the secondary lumen including

Art Unit: 3768

tantalum wire (col. 6, ll. 6-14). Herweck further teaches using titanium as the marker device (col. 6, ll. 24-30).

20. As state above, in the field of implantable devices, the obviousness of the similarities and interchangeability of wires, metals, radioactive boluses, powders, and the like that are well known to enhance the visibility or applicability of otherwise non-radiopaque or MR imagable implants or devices would be apparent to one of ordinary skill in the art. Therefore, the examiner stands it would have been obvious to one of ordinary skill to modify the detectable and bioabsorbable marker of Fulton in view of the tantalum treated bioabsorbable plug teachings of Herweck. The motivation to modify Fulton in view of Herweck would have been to improve visibility or applicability of the marker using known radiopaque or MR imageable agents including the tantalum wire of Herweck or any other biocompatible marker device known in the art.

21. Claim 259 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton et al. (Pub. No.: 2002/0058883) in view of Herweck et al. (USPN 5,320,100) as applied to claim 254 above, and further in view of Stinson et al. (USPN 6,174,330).

22. Fulton in view of Herweck teach all the limitations of the claimed invention except for expressly teaching that the echogenic body comprises a material selected from the group consisting of polyglycolide, PGA, polylactide, PLA, poly caprolactone, polydioxanone, polylactide-co-glycolide, block or random copolymers of PGA and PLA.

Art Unit: 3768

23. In a related field of endeavor, Stinson teaches a bioabsorbable marker (Abstract; Figs. 1-14). Stinson also teaches that the marker may have a body comprising a material selected from the group consisting of polyglycolide, PGA, polylactide, PLA, poly caprolactone, polydioxanone, polylactide-co-glycolide, block or random copolymers of PGA and PLA (col. 2, l. 50- col. 3, l. 30; Figs. 1-14).

24. It would have been obvious to one of ordinary skill in the art to modify the collagen of Fulton in view of Herweck in view of the material selected from the group consisting of polyglycolide, PGA, polylactide, PLA, poly caprolactone, polydioxanone, polylactide-co-glycolide, block or random copolymers of PGA and PLA of Stinson. The motivation to modify Fulton in view of Herweck with Stinson would have been to use known compounds to improve tailor biocompatibility for various medical scenarios, as taught by Stinson.

### ***Response to Arguments***

25. Applicant's arguments, filed 10/21/2010, with respect to the rejection(s) of claim(s) 237-250 under at least Fulton in view of Robinson have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Herweck.

26. The Examiner acknowledges that Fulton in view of Robinson do not expressly teach a unitary piece of metal. However, the use of permanently implantable tantalum wire is well known, as evidenced by Herweck. Accordingly, claims 237-260 are rejected on the grounds set forth above.

Art Unit: 3768

27. The Examiner also acknowledges that McKay does not expressly teach sing titanium as a marker. Accordingly, this ground of rejection has been withdrawn.

However, the use of permanently implantable tantalum wire is well known, as evidenced by Herweck. Accordingly, claims 240 and 250 are rejected on the grounds set forth above.

28. Applicant alleges that the double patenting rejections of claims 237-250 are baseless. Here, Applicant merely queries the Examiner to answer why have the 3 patents used in these double patenting rejections issued on what the Examiner considers to be the same invention. In response, the Examiner notes that the relationship between the 8 applications and the 3 patents is not in question by the above Double patenting rejection. It is the present application's overlapping subject matter with each of the above applications and patents. A quick review of the claims in each of the 8 applications and 3 patents reveals that indeed there is overlapping subject matter. Accordingly and because no further arguments have been set forth, the double patenting rejections stand. The Examiner suggests filing the necessary terminal disclaimers to facilitate prosecution.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number

Art Unit: 3768

is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768